REMARKS

In the Claims:

Claim 1 is cancelled herein without disclaimer or prejudice to pursuing the invention of claim 1 in continuing or divisional applications. Claims 3, 5-7, and 23-25 are pending. Claims 3 and 24 are amended herein for purposes of increasing the clarity of the claims. Specifically, claims 3 and 24 are amended to clarify that the claimed method is used to prepare a standardized extract. No new matter is added by amendment of claims 3 and 24 and support for the amendment may be found throughout the specification, including at paragraphs 0002, 0005, 0035, 0040-0042 and original claims 10, 12, 15, and 18.

Claims 3 and 24 also are amended herein to clarify that the concentration of the marker compound is greater than zero and acceptable for preparing a standardized extract of the medicinal plant. No new matter is added by this amendment and support for the amendment may be found throughout the specification including at paragraph 0017 on page 4, at Table I on page 6, at paragraphs 0024 and 0025 on page 7, and at paragraph 0032 on page 9.

Claim Rejections:

35 U.S.C. § 112, ¶ 1:

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. Claim 1 is cancelled herein without disclaimer or prejudice to the filing of continuation or divisional applications. Applicants have therefore overcome this ground of rejection and respectfully request it be withdrawn.

35 U.S.C. § 112, ¶ 2:

Claims 1, 3, 5-7, and 23-25 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office action

alleges that the claims are indefinite because they do not recite what level of marker compound is acceptable.

Applicants respectfully disagree with this ground of rejection. However, to expedite prosecution, claim 1 is cancelled herein without disclaimer or prejudice to the filing of continuation or divisional applications. Applicants have therefore overcome this ground of rejection for claim 1 and respectfully request it be withdrawn. In addition, Applicants have herein further clarified that the claimed concentration of marker compound is greater than zero and acceptable for preparing a standardized extract. According to Section 2173.05(b) of the MPEP, the "[a]cceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification." As amended, the claims are not indefinite because one of ordinary skill in the art will know what levels of a marker compound are greater than zero and acceptable for preparing a standardized extract. For example, at paragraph 2, the specification teaches that *Echinacea* extracts are standardized to contain a known concentration of one or more of chicoric acid, polysaccharides, or alkylamides." Indeed, plant extracts are standardized as a means of ensuring uniformity. The specific concentration of a marker compound is used to ensure that extracts of a particular plant from a single provider, for example the Assignee Access Business Group International, are uniform because they all meet a particular "standard," *e.g.* all have a particular concentration of a marker compound. In some instances, it may be preferable to standardize extracts to have the highest possible concentration of a marker compound. In other instances, it may be preferable to standardize extracts to have a lower concentration of a marker compound. Regardless of whether an extract is standardized to a highest concentration, a lower concentration, or some other concentration, for standardization, the most important attribute is that all extracts from a single source (*e.g.* a single provider) have the ***same*** concentration, wherein that concentration is greater than zero.

For example, the present application describes using chicoric acid as a marker compound for an *Echinacea* extract. Any concentration of chicoric acid greater than

zero may be acceptable for preparing a standardized *Echinacea* extract so long as all extracts from a single source (*e.g.* a single provider) are prepared so that they have the same concentration of chicoric acid. Table 1 and paragraphs 22 and 24 of the present application report that the levels of chicoric acid do not vary greatly in *Echinacea* from plant to plant or maturation stage to maturation stage. Indeed, the values reported at Table 1 range from 3.49 $\pm$ 0.09 % to 3.54 $\pm$ 0.14 %. Hence, in one example, a concentration of marker compound that is greater than zero and acceptable for preparing a standardized *Echinacea* extract may be 3.5 % chicoric acid. So long as all prepared extracts meet the standard of 3.5% chicoric acid, that standardization level is acceptable. The same would be true if the extract were standardized to 3.4% or 3.6% chicoric acid, or even if some other concentration percentage were selected.

Thus, because one of ordinary skill in the art would understand what is claimed by reference to a concentration of marker compound that is greater than zero and acceptable for preparing a standardized extract of the medicinal plant, the claims are not indefinite. Applicants have overcome this ground of rejection and respectfully request that it be withdrawn.

35 U.S.C. § 103

Claims 1, 3, 5-7 and 24 stand rejected under 35 U.S.C. § 103 as allegedly obvious in view of Seidler-Lozykowska *et al.* or Dou *et al.* in combination with Ringer *et al.* At page 6 of the Office action, the Examiner states that "there is no particular step that requires standardization of the Echinacea extract."

Applicants respectfully disagree with this ground of rejection. Claim 1 is cancelled herein without disclaimer or prejudice to the filing of continuation or divisional applications. Applicants have therefore overcome this ground of rejection for claim 1 and respectfully request it be withdrawn. With regard to claims 3, 5-7 and 24, according to Section 2141 of the MPEP, when applying 35 U.S.C. 103, the following tenets of patent law must be adhered to: (A) The claimed invention must be considered as a

whole; (B) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) reasonable expectation of success is the standard with which obviousness is determined. *Hodosh v. Block Drug Co., Inc.,* 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

Under these standards, the claims are not obvious in view of the cited references. First, the claimed invention as a whole is a method for determining optimal harvest window of *Echinacea*, based on selecting a plant maturation stage that has both a concentration of a marker compound that is greater than zero and acceptable for preparing a standardized extract, and immunostimulatory activity. The claimed method also includes a step of preparing a standardized extract at that selected maturation stage.

The cited references as a whole do not teach this method. Specifically, two of the cited references, Seidler-Lozykowska and Dou, examine when the greatest levels of typical marker compounds (i.e. polyphenolics, phenolic acids such as chicoric acid, caffeic acid, etc.) used to standardize extracts may be obtained and from which specific parts of the plant they may be obtained. The third reference Rininger, teaches that standardized *Echinacea* extracts are "inactive" for immunostimulatory activity. Rininger also teaches that the compounds commonly used to standardize *Echinacea* extracts, *e.g.* chlorogenic acid, do not possess any immunostimulatory activity. In contrast, Rininger further teaches that *non-standardized Echinacea*, specifically *Echinacea* herb and root powders, *was* found to be immunostimulatory. Thus, Rininger teaches that although *Echinacea* may possess immunostimulatory activity, ***standardized*** extracts of *Echinacea* do **not** possess any such activity.

When taken as a whole, as they must be, *see* MPEP § 2141, it is clear that these references do not suggest either the desirability of the claimed method or a reasonable expectation of success. Specifically, Rininger teaches that neither standardized *Echinacea* extracts nor the common marker compounds used for standardization of

Echinacea extracts exhibit immunostimulatory activity. Seidler-Lozykowska and Dou both teach means for producing *Echinacea* extracts with the highest concentration of compounds used to standardize *Echinacea* extracts. Thus, one of ordinary skill in the art would not, based on the teachings of the cited references, expect the claimed method of optimizing harvest window of a plant, *e.g. Echinacea,* by selecting a plant maturation stage that produces a level of marker compound acceptable for preparing a standardized extract, yet also maintains immunostimulatory activity, to be successful.

Indeed, the United States Court of Appeals for the Federal Circuit addressed a similar situation in *In re Grasselli,* 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). That case involved a claim to a catalyst containing both iron ("I") and alkali metal ("AM"):

> ***CLAIM:*** catalyst + I + AM

The PTO rejected that claim as obvious in view of two references. The court found the rejection was improper because the references could not be combined to reach the claimed invention with any success. Specifically, the first reference taught that antimony ("A") is interchangeable with AM while the second reference taught a catalyst with I but expressly excluded A:

> ***Reference 1:*** A = AM
> ***Reference 2:*** catalyst + I but CANNOT have A
> ***Thus, the combined teaching of Reference 1 and 2 =*** catalyst +1 but CANNOT have AM

The combined teaching of the references was a catalyst with I but without A. Thus, the claimed invention was not obvious.

In re Grasselli directly applies here. The claims are to a method that involves combining two characteristics of *Echinacea*: (1) standardization of the plant ("S") and (2) immunostimulatory activity of the plant ("ISA"):

CLAIM AT ISSUE: method of optimizing harvest window by selecting plant maturation stage with levels of a marker compound > 0 and acceptable for S and ISA

Two references, Seidler-Lozykowska and Dou teach maximizing levels for S while the third reference Rininger teaches that standardized *Echinacea* extracts do not have immunostimulatory activity. Thus, the combined teaching is that if an *Echinacea* extract is standardized, then it does not have immunostimulatory activity.

References 1 and 2 – Seidler-Lozykowska/Dou: maximize levels for S
Reference 2 – Rininger: S does not have ISA
Combined teaching of Reference(s) 1/2 and 3: If S, then no ISA

Thus, as discussed above, these references cannot be combined to render the claimed invention obvious because the combined teaching is that standardized *Echinacea* extracts do not have immunostimulatory activity.

Claims 3, 5-7, and 23-25 are not obviousness in view of the cited references. Applicants have overcome this ground of rejection and respectfully request that it be withdrawn.

SUMMARY

Applicants believe that currently pending claims 3, 5-7, and 23-25 are patentable. The Examiner is invited to contact the undersigned attorney for Applicants via telephone if such communication would expedite allowance of this application.

Respectfully submitted,

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